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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,610	09/26/2001	Adam S. Cantor	56032US022	8132

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,610	CANTOR ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/14/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,16-18,28-31,35-37 and 39-91* is/are pending in the application.

4a) Of the above claim(s) *48-51 and 55-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,16-18,28-31,35-37,39-47 and 52-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for RCE and amendment, both filed 06/14/2006.

Claims 1-9, 16-18, 28-31, 35-37 and 39-91 are pending.

Claims 48-51, and 55-91 are withdrawn from further consideration. Claims 48-51 are drawn to an invention that is independent or distinct from the invention of claim 1-9, 16-18, 28-31, 35-37, 39-47, and 52-54 because claims 48-51 do not require the copolymer comprising two monomers (i) alkyl acrylate monomer and (ii) ethylenically unsaturated monomer as required by claims 1, 35-37 and 54. Claims 48-51 require acrylate polymer only.

The examiner is not clear regarding the status of claims 55-91 if they are withdrawn or canceled and been presented in a divisional application. If the claims are withdrawn as shown by the amendment, then the text of the claims need to be included in the listing of the claims and provided with the proper status identifier, i.e. "withdrawn".

Claims 52 and 53 have been added to the prosecuted claims.

Claims 1-9, 16-18, 28-31, 35-37, 39-47, and 52-54 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/14/2006 has been entered.

Specification

2. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-9, 16-18, 28-31, 35-37, 39-47 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/08229 ('229) by itself or in view of US 5,993,849 ('849).

WO '229 teaches a transdermal drug delivery device comprising a backing and a matrix comprising a copolymer, a softener and a drug (page 2, lines 5-23). The copolymer comprises 40-90% of one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 10 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 10 carbon atoms in the alkyl group and up to 60% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomers. The composition further comprises more than 30% of a macromonomer copolymerizable with the A and B monomers (page 2, lines 5-23). The A monomers are taught on page 4, lines 3-14 with isooctyl acrylate preferred. The B monomers are taught on page 4, line 15 through page 5, line 12, with hydroxyethyl acrylate preferred.

The macromonomers are taught on page 5, line 13 through page 8, line 28. Polymethylmethacrylate macromonomers are preferred (page 6, lines 17-18). The softeners of the delivery device affect skin penetration rate and include fatty acids, fatty alcohols, fatty acid esters such as methyl laurate and tetraglycols (page 8, line 29 - page 10, line 15). Softeners can be included in amounts up to 60% by weight of the matrix (page 10, lines 7-15). WO '229 further contemplates various drugs for delivery by the device including analgesics such as fentanyl (page 12, line 28). The drug is present in the transdermal device in an amount of about 0.01 to about 30 percent by weight (page 13, lines 16-18). Also, the drug is substantially fully dissolved, and the matrix is substantially free of solid undissolved drug (page 13, line 18-20). The transdermal device comprising the pressure sensitive adhesive disclosed by WO '229 allows dissolution of drug and relatively heavy loading with oily excipients, maintains contact with skin, and can be removed cleanly from the skin (page 3, lines 11-15).

Although WO '229 listed fentanyl as a possible acceptable drug for transdermal delivery by the disclosed transdermal copolymer composition, however, WO '229 does not specifically exemplify fentanyl. The reference exemplifies nicotine and levonorgestrel. WO '229 recognized the suitability of fentanyl to be delivered transdermally in an adhesive copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer.

US '849 teaches adhesive composition suitable for transdermal delivery systems and having improved tolerance on the skin and improved controlled release of the active substance (abstract; col.2, lines 15-19). The composition comprises acrylate copolymer

and preferred drugs are exemplified by fentanyl and nicotine (claim 10). Therefore the art recognized the equivalency between nicotine and fentanyl in terms of drugs suitable for transdermal delivery from an acrylate copolymer composition.

Therefore, it would have been obvious to one having ordinary skill in the art at the of the invention to provide transdermal delivery composition comprising copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer as disclosed by WO '229, and use the composition to deliver fentanyl, motivated by the teaching of WO '229 that transdermal device comprising the disclosed pressure sensitive adhesive copolymers allows dissolution of drug and relatively heavy loading with oily excipients, maintains contact with skin, and can be removed cleanly from the skin, with reasonable expectation of having transdermal delivery composition comprising copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer and fentanyl wherein the device allows dissolution of fentanyl, as desired by applicants, maintains contact with skin, and can be removed cleanly from the skin.

Additionally one having ordinary skill in the art at the time of the invention would have been motivated to provide transdermal delivery composition comprising copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer as disclosed by WO '229, and use the composition to deliver fentanyl as disclosed by US '849, motivated by the teaching of US '849 that fentanyl is one of the preferred drugs to be delivered in acrylic copolymer adhesive as evident by reciting fentanyl in the claims, motivated by the teaching of US '849 that such a transdermal delivery system has improved controlled release of the active substance with reasonable expectation of having

transdermal delivery composition comprising copolymer of alkyl acrylate monomer and ethylenically unsaturated monomer and fentanyl with improved controlled release rate of fentanyl.

Response to Arguments

6. Applicant's arguments filed 06/14/2006 have been fully considered but they are not persuasive. Applicants traverse the rejection of claims 1-9, 16-18, 28-31, 35-37, 39-47 and 52-54 by arguing that WO '229 does not describe device for delivering fentanyl and US '849 does not provide single working example for delivering fentanyl. Applicants argue that fentanyl and nicotine are not equivalent.

In response to this argument, it is argued that a conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969). The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Regarding equivalency between fentanyl and nicotine, the art shows that they are equivalent in the term of both being able to be delivered transdermally, and both being able to be delivered from acrylate copolymer adhesive matrix or layer.

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,139,866 disclosed that fentanyl can be delivered from acrylate copolymer comprising at least two components selected from 2-ethylhexyl acrylate, vinyl acetate, ethyl acrylate, methacrylate, methoxyethyl acrylate, and acrylic acid (abstract; col.2, line 67; col.3, lines 1-5, example 1).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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ISIS GHALI
PATENT EXAMINER